

Appl. No. 10/618,281
Amdt. dated June 6, 2006
Reply to Office action of December 7, 2005

Page 4

REMARKS

The Invention.

The present invention provides methods of cleaving a peptide bond in a desired protein and for treating a disease or disorder with a protease having an amino acid sequence of SEQ ID NO:11.

Status of the Application.

Claims 1 and 17 are pending in the application. Claims 2-16 and 18-20 have been cancelled as drawn to a non-elected invention without prejudice and Applicants reserved the right to file further continuation applications on any subject matter disclosed in the instant application or on the subject matter of any previously or presently cancelled claim. Claims 1 and 17 have been amended to remove non-elected subject matter. Applicants assert new matter has not been introduced by the amendment.

Election/Restriction.

Claims 2-16 and 18-20 have been withdrawn by the Examiner as being drawn to a non-elected invention. Applicants hereby cancel Claims 2-16 and 18-20 without prejudice. Applicants reserve the right to pursue the originally filed, similar and/or broader Claims in the future.

Specification.

The disclosure was objected to as containing an embedded hyperlink and/or other form of browser-executable code. Applicants have amended the specification to remove the hyperlinks. Withdrawal of the objection is respectfully requested.

35 U.S.C. §101.

Claims 1 and 17 stand rejected under 35 USC §101 as failing to be supported by either a specific or asserted utility or a well established utility. Specifically, the Examiner asserts that the specification discloses not specific *in vitro* (Claim 1) or *in vivo* (Claim 17) utility. Applicants respectfully traverse.

Applicants have provided the structure (i.e., the amino acid sequence; see SEQ ID NO:11) and methods of assaying the proteins enzymatic activity (i.e., various assays referenced throughout the specification as filed; see for example page 29). Moreover, serine proteases (such as SEQ ID NO:11) are well known to be involved in various physiological

Appl. No. 10/618,281
Amdt. dated June 6, 2006
Reply to Office action of December 7, 2005

Page 5

conditions. See page 11. As such, substrates are well known. Therefore, one of skill in the art would know how to assay the enzymatic activity of the presently claimed protein. Withdrawal of the rejection is respectfully requested.

35 U.S.C. §112, first paragraph.

Written Description

Claims 1 and 17 stand rejected under 35 USC §112, first paragraph as failing to be described in the specification. Specifically, the Examiner asserts that one skilled in the art would not know how to use the claimed invention. Applicant respectfully traverses.

Indeed, as indicated previously, Applicant must respectfully disagree with the Examiner's argument and rationale, as the present Specification teaches that SEQ ID NO:11 is a serine protease. One skilled in the art would understand that SEQ ID NO:11 proteolytic activity could be measured using standard substrates for a serine protease and would find use in conditions that may be treated by serine proteases (See e.g., page 11 of the Specification). As noted above, Applicants have provided methods for determining proteolytic activity (See e.g., page 29 of the Specification and specifically THE HANDBOOK OF PROTEOLYTIC ENZYMES, 1998, Academic Press, San Diego that was incorporated by reference). Applicant respectfully submits that both the structure and function of the protease claimed are provided in the Specification, as the amino acid sequence (base structure) and function (proteolytic activity) are well-described throughout the Specification. Therefore, Applicants believe that the Specification fully describes the claimed invention. Withdrawal of the rejection is respectfully requested.

Enablement

Claims 1 and 17 stand rejected under 35 USC §112, first paragraph because the Examiner believes that the specification does not reasonably provide enablement for the full scope of the claimed invention. Specifically, the Examiner asserts that Claims 1 and 17 contemplate unlimited and unguided experimentation. Applicants respectfully traverse.

The fact that experimentation may be complex does not necessarily make it undue, if the art engages in such experimentation (MPEP 2164.01 and cites therein). Applicants submit that by teaching how assay SEQ ID NO:11's proteolytic activity and what conditions SEQ ID NO:11, as a serine protease, may find use in, more than sufficient teaching is

Appl. No. 10/618,281
Amdt. dated June 6, 2006
Reply to Office action of December 7, 2005

Page 6

provided as to how to make and use the present invention. Indeed, as the MPEP states at 2164.01(b):

As long as the specification discloses at least one method for making and using the claimed invention that bears reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Thus, the fact that Applicants do not explicitly provide examples regarding every substrate that finds use with the present invention does not render the present claims unpatentable. The Specification teaches the structure (i.e., the amino acid sequence) of SEQ ID NO:11 and assay methods, as determined using standard enzyme activity assays; See e.g., page 29 and throughout the Specification. Selection of the substrate protein to be cleaved is left to the user of the present invention, as well as the selection of the assay to determine the enzymatic activity. Applicants submit that the Specification provides what is needed so that use of the methods is well within the skill of those in the art. Thus, Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. §112, second paragraph.

Claims 1 and 17 are rejected under 35 USC §112, second paragraph as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that Claim 1 is indefinite in its usage of the phrase "a desired protein" and Claim 17 is indefinite in its usage of the phrase "administering to a patient in need of such treatment." Applicants respectfully traverse.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999), "it is well-established that the determination whether a claim is invalid as indefinite 'depends on whether those skilled in the art would understand the scope of the claim when the claim is

Appl. No. 10/618,281
Amdt. dated June 6, 2006
Reply to Office action of December 7, 2005

Page 7

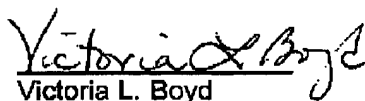
read in light of the specification." quoting *North Am. Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993). See also, *Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1371 (Fed. Cir. 2005), wherein the Federal Circuit overturned an invalidity decision, concluding that "one of ordinary skill in the art would readily ascertain from the written description of the patents that the "transverse sectional dimension" calls for a two-dimensional measurement."

An important consideration is whether the terms in a claim adequately define to one skilled in the art the metes and bounds of the claim. Here, Applicants have provided guidance readily understood by the skilled artisan. One of skill in the art would not have trouble understanding the meaning of either phrase as used in the claims. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In light of the above amendments, as well as the remarks, the Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7615.

Respectfully submitted,
GENENCOR INTL., INC.


Victoria L. Boyd
Registration No. 43,510

Date: June 6, 2006

Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94304
Tel: 650-846-7615
Fax: 650-845-6504